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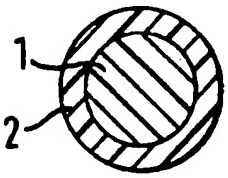
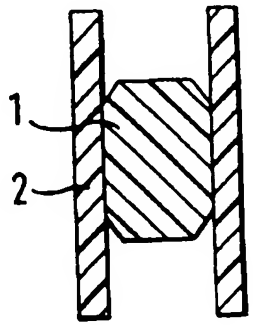
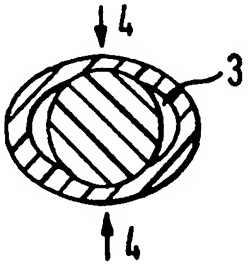
(54) Title: INFUSION APPARATUS COMPRISING A DEFORMABLE TUBE

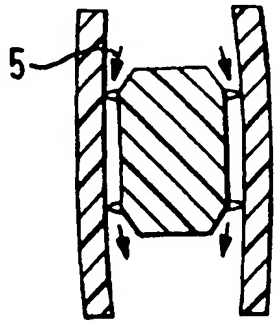
(57) Abstract

The apparatus includes a blocking element (2) located in an infusion tube (1). The tube (1) is deformable via the application of an external force so as to create a gap (3) between the blocking element (2) and the inner wall of the tube (1) through which a fluid can pass.









INFUSION APPARATUS COMPRISING A DEFORMABLE TUBE

The present invention relates to an apparatus comprising a deformable tube and, in a preferred embodiment, to an infusion apparatus comprising a deformable tube.

An infusion appliance is necessary for the enteral or parenteral infusion of liquids to patients in hospitals and ambulances. The necessary quantity is administered at a predetermined rate, e.g. drops per minute, ml per hour. The infusion liquid goes from the infusion container to the patient by way of an infusion set. The set must be inserted in the infusion appliance before the infusion and removed from the appliance after the infusion. It is important that throughout the treatment infusion liquid never be allowed to flow uncontrolled into the patient. The normal practice is to use a roller clamp which must be closed before insertion of the set until the infusion appliance takes over control. The clamp is then opened manually. The roller clamp must again be closed at the end of the infusion before removal of the administration set from the infusion appliance. Also, modern infusion appliances are fitted with a flow clamp which stops flow when the door (of the appliance) is opened. However, when the administration set is to be removed from the appliance, this clamp must first be opened and if the roller clamp (on the administration set) has not previously been closed, uncontrolled flow will take place.

Various manufacturers (of infusion appliances) have endeavoured to incorporate a flow-stop clamp in the administration set. However, the flow barriers which have been developed are relatively expensive. Either a mechanism is provided in the set and automatically closes

a kind of lock with a spring mechanism which is kept open when the set of the infusion appliance is inserted, or, in other solutions to the problem, the set is clamped by means of an external mechanism, a feature which in some cases simplifies the mechanism of the set but which requires the presence of a relatively elaborate mechanism in the infusion appliance.

All the previous constructions have the following serious disadvantages:

Known infusion sets are single use articles - i.e., they must be discarded after being used only once. The introduction of prior art mechanisms fitted to the sets increases operating costs considerably since the entire mechanism is discarded after each treatment.

Operation of the mechanism is often complicated and is an additional burden on staff; some mechanisms malfunction in the event of incorrect operation and so the additional safety turns into a risk.

Each mechanism can be used only with the dedicated infusion appliance since it requires a special triggering mechanism therein. Also, insertion into the infusion appliance is much more complicated than in the case of conventional sets.

The present invention seeks to overcome or at least to alleviate one or more of the aforesaid disadvantages.

According to the present invention there is provided an apparatus comprising a deformable tube and a blocking element located in said tube which is shaped to block the

flow of fluid (i.e. gas or liquid) through the tube unless a force is applied to deform said tube, the blocking element being less deformable than the tube when said external force is applied to deform the tube. Preferably the apparatus is a medical apparatus (e.g. an infusion apparatus), although it may be a non-medical apparatus since the present invention is generally applicable where deformable tubing is used.

The apparatus may include deforming means for deforming the tube to allow fluid to flow past the blocking element. The deforming means preferably comprises an element having a generally wedge-shaped cross-section. Thus it may include, for example, a wedge-shaped member mounted on an arm and arranged to press the tube against another member (e.g. against a member having a flat surface).

The deforming means may alternatively be in the form of a clip adapted to be attached to the tube so as to apply pressure to it.

Where the apparatus is not provided with a deforming means it can still be operated since an operator can squeeze the tube in the vicinity of the blocking member to allow fluid to flow through the tube.

In one embodiment of the present invention the tube is provided with a surround so that an external force can be applied to the surround in order to deform the tube. The surround does not contact fluid and can therefore be re-used without fear of contaminating said fluid. The surround is preferably removably mountable to the tube.

In order to retain the blocking element at a desired position in the tube, retaining means may be provided. Thus the tube may have a bore which is narrower above and below the blocking element than elsewhere in order to hold the blocking element in place. Alternatively the blocking member may be attached to attachment means (e.g. to an elongate member such as a rod, a wire, or a thread) which maintains the blocking element at a given position within the tube.

The blocking element is preferably formed from a plastics material (e.g. silicone or PVC). However said material should be less deformable than the tube in which the blocking element is located. The attachment means may be attached to the blocking member at one end and to another part of the infusion apparatus at another end in order to keep the blocking element in position.

The present invention is relatively simple to operate and easy to produce. The ease of operation reduces the likelihood of malfunctioning due to mis-handling.

An infusion apparatus according to the present invention can be produced by modifying prior art infusion apparatuses, since it is relatively simple to insert a blocking element as described herein into an infusion tube of such an apparatus. A prior art apparatus can also be easily provided with a wedge-shaped member, a clip or other means of deforming the tube.

In addition to the components specifically described above, the apparatus may include additional components. Typically one or more of the components discussed in the paragraph below may be provided.

The apparatus may comprise a fluid reservoir (e.g. a bottle or a bag), a drip chamber, means for inserting into the fluid reservoir to allow fluid to flow to the drip chamber, a drop detector, a connector for connecting an infusion tube with a cannula, catheter or needle (e.g. a luer-lock connector). A pump may also be provided. The apparatus may be provided as a kit of parts in ready to assemble form and may include instructions for use.

A preferred apparatus of the present invention is an administration set. The administration set will typically comprise a drip chamber (which normally will be provided with a spike or other device for inserting into a fluid container), a drop detector, and a tube and blocking element as described in claim 1.

The present invention will now be described by way of example only with reference to the accompanying drawings wherein:

FIGURE 1 is a cross-section through a tube of an apparatus of the present invention, having a blocking element of generally circular cross-section located in the tube, which acts to block the flow of liquid through the tube.

FIGURE 2 is a longitudinal section through the tube illustrated in Figure 1.

FIGURE 3 is a cross-section though the tube illustrated in Figure 1 which has been deformed by an external force (indicated by the arrows). The force may be applied via a clip (not shown).

FIGURE 4 is a longitudinal section through the

deformed tube shown in Figure 3.

FIGURE 5 is a cross-section showing the tube shown in Figure 1 having a surround which has been slid over the tube.

FIGURE 6 is a cross-section showing the tube with surround shown in Figure 5, which has been deformed by an external force (indicated by the arrows). The force may be applied via a clip (now shown).

FIGURE 7 is a cross-section showing a tube with a surround which has been deformed, the surround having a different shape from the surround illustrated in Figure 6.

FIGURE 8 is a cross-section showing a wedge-shaped member acting to deform a tube of the apparatus of the present invention by pressing the tube against a flat surface.

FIGURE 9 shows an administration set which may incorporate a blocking element to provide an apparatus of the present invention.

FIGURE 10 shows a cross-section showing an alternative arrangement to that shown in Figure 8. Here the member acting to deform the tube can be considered as comprising two generally wedge-shaped parts.

Referring now to Figs. 1 and 2 there is shown a blocking element (1) which is in the form of a plastics member having a round cross-section, and which has been introduced into a tube (2) of an infusion set so as to

block the bore of the tube (2). The blocking element (1) can be of slightly larger cross-section than the bore of the tube (2) in order to be lodged therein. There is no flow of liquid through tube (2) in this state.

However when pressure (4) is applied to the tube wall the tube wall is deformed (Figs. 3 and 4). Since the blocking element (1) is harder than the tube (2) this deforms either less than the tube wall or not at all. Thus, a gap (3) opens and an infusion liquid can flow (5) through the gap (3) while pressure continues to be applied to the tube (2). When this pressure is no longer applied tube (2) returns to a state in which its bore is blocked by the blocking element (1) so that flow of liquid through tube (2) is prevented. By gradually releasing the pressure on the tube (2) the flow of liquid therethrough can be varied through a range from maximum flow to complete blockage.

The blocking element (1) will normally have rounded or bevelled edges to prevent damage to the inner wall of tube (2). This can be seen from Figs. 2 and 4.

Figs. 5, 6 and 7 illustrate a preferred embodiment of the present invention in which a resiliently deformable surround (6,7) is provided around the tube (2). This may be of annular cross-section for example (for example it may be in the form of a ring or a cylinder), although this is not essential (e.g. it may have a generally oval cross-section), and allows pressure to be applied to the tube (2) via a member which does not contact the tube (2) directly, but which contacts the surround (6,7). The surround (6,7) does not contact infusion liquid present in tube (2) and can therefore be re-used without worrying about contamination of the infusion liquid.

The surround (6,7) may simply be slid over the tube (2) prior to infusion.

Fig. 8 shows a cross-section though a tube (2) of an apparatus of the present invention when being deformed by pressure applied by a member (8) having a wedge shaped cross-section. The member (8) acts to press the tube (2) against a stopping surface (9). It deforms the wall of tube (2) to deform so as to provide a gap (10) between the wall and the blocking element (1), through which liquid can flow.

Arrow A indicates the direction in which the member (8) is moved to apply pressure to the tube (2) (in order to allow flow of liquid through the tube (2)) and arrow B indicates the direction in which the member (8) is moved in order to release this pressure. When the pressure is released the resilience of tube (2) causes it to close gap (10) and thereby to prevent flow of liquid through the tube (2).

Turning now to Figure 9, there is shown a typical administration set (30). The administration set (30) includes a spike (31) for puncturing a reservoir of infusion fluid (not shown). The spike is part of a drip chamber (32).

The drip chamber (32) is provided with a sealable air inlet (33) which has a bacterial filter and filter (34) is also provided at the base of the drip chamber (32). The drip chamber (32) is connected to a length of flexible tubing (33) which is typically formed of PVC and which may have a length of around 40 cm. A roller clamp (36) is shown attached to the tubing (37) and enables the flow of infusion fluid to be stopped when desired.

A silicone pumping insert (37) is included having connectors (38,39) at either end so that it is removably connected to other tubing (for ease of assembly prior to sterilization). This section can be modified to include a blocking member as described in relation to Figures 1 to 8 above. There is then a further section of tubing (40) and the administration set terminates in a luer lock connector (41).

Figure 10 shows an alternative arrangement to that shown in Figure 8. Here a member (50) is shown which can be considered to have two generally wedge-shaped parts (51, 52).

This member (50) can be moved in the direction of arrow A towards a stopping surface (55) so as to deform the wall of a tube (53). This deformation allows a gap (56) to appear through which liquid can flow past a blocking element (54).

When the member is moved in the direction of arrow B the gap (56) closes so that the blocking element (54) acts to block the flow of liquid through the tube (53).

CLAIMS

1. Apparatus comprising a deformable tube and a blocking element located in said tube which is shaped to block the flow of fluid through the tube unless a force is applied to deform said tube, the blocking element being less deformable than the tube when said external force is applied to deform the tube.

2. Apparatus according to claim 1 wherein the tube is resiliently deformable so that when the external force has been applied and then removed from the tube, the tube deforms so that its inner wall contacts the blocking element and the flow of fluid through the tube is thereby blocked.

3 Apparatus according to claim 1 or claim 2 wherein the force is provided by a deforming means.

4. Apparatus according to claim 2 wherein the deforming means comprises a member which is arranged to press the tube against a surface so as to deform the tube and to allow fluid to flow past the element.

5. Apparatus according to claim 3 or claim 4 wherein the deforming member includes a portion which has a generally wedge-shaped cross-section.

6. Apparatus according to claim 3, 4 or 5 wherein the deforming means is in the form of a clip which is adapted to be attached to and released from the tube.

7. Apparatus according to any preceding claim wherein the tube is provided with a resiliently deformable surround.

8. Apparatus according to any preceding claim which is an infusion apparatus for infusing liquid to a patient.

9. Apparatus according to any preceding claim which is an infusion set.

10. Apparatus substantially hereinbefore described with reference to the accompanying drawings.

11. A device for controlling the flow in a tube, characterised in that an element completely fills the internal cross-section of the tube and closes the flow and when an external force is applied the flow is released by deformation of the tube.

12. A device according to claim 11, characterised in that when the force is removed the system automatically cuts off the flow through the restoring force of the tube.

13. A device according to claim 11 or 12, characterised in that an external adapter improves the closed position and open position as regards their effect and ease of operation.

FIG. 1

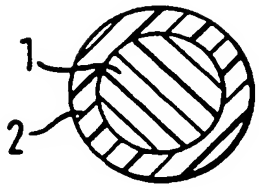


FIG. 2

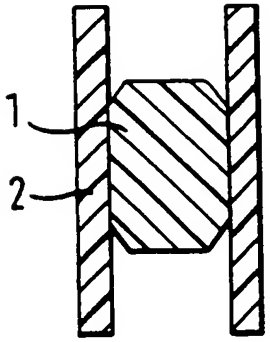


FIG. 3

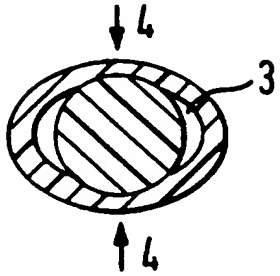


FIG. 4

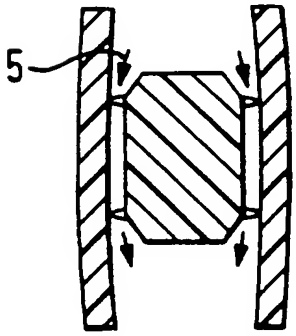


FIG. 5

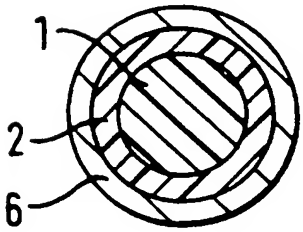


FIG. 6

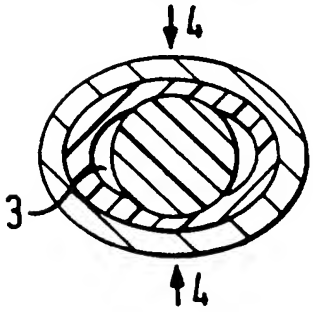
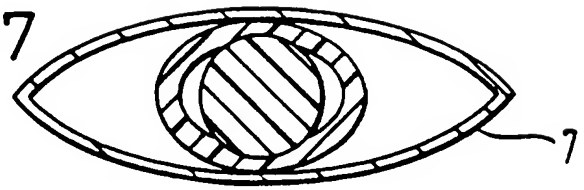


FIG. 7



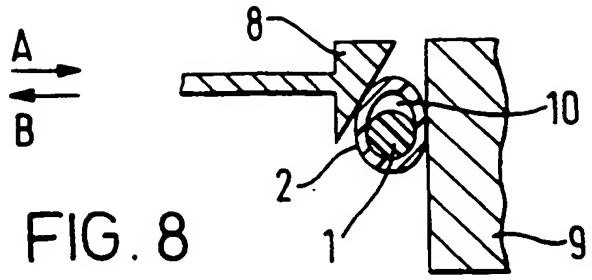


FIG. 8

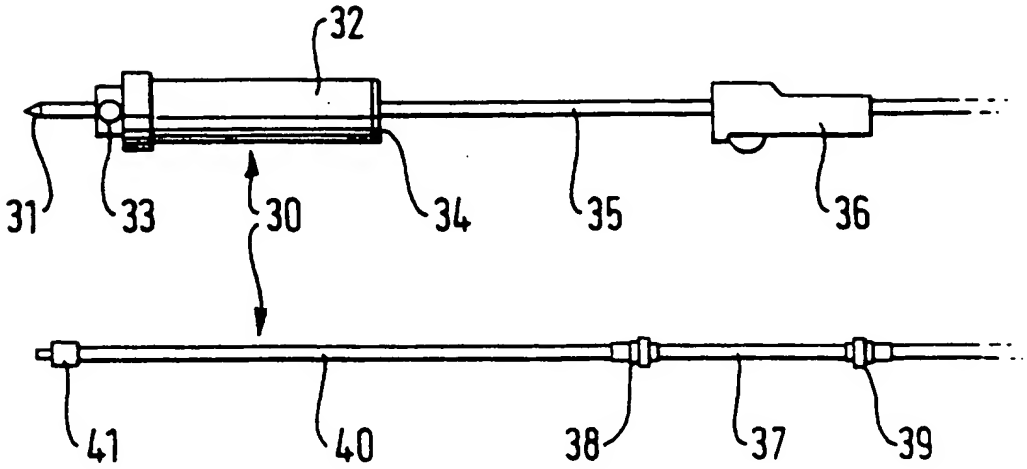


FIG. 9

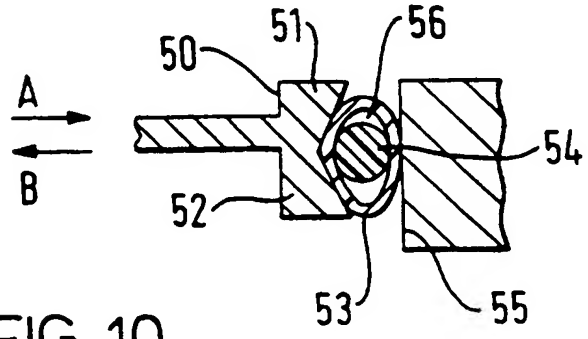


FIG. 10